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Microbiological Testing - Medistri

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For many years, healthcare quality has been enhanced by medical devices. These devices are made with strict safety and risk evaluation processes to ensure they work as intended and safeguard patients' health. To maintain high quality control standards, manufacturers have to check their medical devices regularly. One of the methods to assess the safety of a device is to look for any harmful microorganisms that might infect the device. This is done by using microbiological tests.

Microbial contaminants are microorganisms that can pose a biological risk to medical devices. Microbiological testing is a way to check for these contaminants and their potential harm. It can involve measuring the amount of microbes, detecting endotoxin, and ensuring sterility.

👉 This is a key part of the quality and safety checks as it helps to prevent or lower the chance of infections to patients. This is also supported by keeping the manufacturing environment and process free of microbes.

Microbiological testing can also be relevant for non-sterile medical devices as they may need to be watched and/or limited for the presence of unwanted microorganisms.

Global medical device regulations require sterility assurance of medical devices. It is essential to have consistent microbiological testing during manufacturing to ensure product quality and patient safety.

Medical devices are products that are used for diagnosis, prevention, treatment, or alleviation of diseases or injuries. They can come into contact with the human body or bodily fluids, which may contain harmful microorganisms that can cause infections or other complications - Microbiological testing is important because it helps to ensure the safety and quality of medical devices. Therefore, microbiological testing is a way to check for the presence and risk of these microbial contaminants and to eliminate or reduce them as much as possible.

✓ A Microbiological test is done by using various methods, such as measuring the amount of microbes on the device (bioburden), detecting toxins produced by bacteria (endotoxin), and verifying the effectiveness of sterilization processes (sterility testing). Microbiological testing is also supported by environmental monitoring and microbial control of the entire manufacturing process, to prevent contamination from the surroundings.

Microbiological testing is not only important for patient health, but also for regulatory compliance and product quality. Global medical device regulations require manufacturers to perform microbiological testing according to international standards and guidelines, such as ISO 10993-7, ISO 11737, ISO 11135 and ISO 17665. These standards specify the methods, criteria, and procedures for microbiological testing of medical devices.

ISO 10993-7 is a standard that relates to microbiological testing of medical devices that are sterilized by ethylene oxide (EO). EO is a gas that can kill microbes but also leave harmful residues on the device. These residues are EO and ethylene chlorohydrin (ECH), which are both toxic and carcinogenic substances. ISO 10993-7 specifies the allowable limits for residual EO and ECH in individual EO-sterilized medical devices, procedures for the measurement of EO and ECH, and methods for determining compliance so that devices may be released. ISO 10993-7 helps to protect patients from the adverse effects of EO and ECH exposure.

Therefore, microbiological testing and ISO 10993-7 are correlated because they both aim to ensure the safety and quality of medical devices, especially those that are sterilized by EO. Microbiological testing checks for the presence and risk of microbial contaminants, while ISO 10993-7 checks for the presence and risk of chemical contaminants. By following these standards and guidelines, manufacturers can demonstrate that their medical devices meet the safety and performance requirements of different markets and regulators.

- ISO 11737: Specifies requirements and provides guidance on the enumeration and microbial characterization of the population of viable microorganisms on or in a health care product, component, raw material or package. It also specifies the general criteria for tests of sterility performed in the definition, validation and maintenance of a sterilization process.
- ISO 11135: Specifies requirements for the development, validation and routine control of an ethylene oxide sterilization process for medical devices. It covers the sterilization of medical devices, which have been exposed to a reduced dose of the sterilizing agent as part of the validation process.
- ISO 17665: Specifies requirements for the development, validation and routine control of a moist heat sterilization process for medical devices. It covers both saturated steam and contained product sterilization processes using water as the sterilizing agent.

By following these standards, manufacturers can demonstrate that their medical devices meet the safety and performance requirements of different markets and regulators. Moreover, microbiological testing can also help manufacturers to improve their product quality and reliability, by identifying and resolving any issues related to microbial contamination.

🌐 To learn more about Medistri's Microbiological testing, visit on our website at www.medistri.swiss or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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